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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STEELE, AMBER D

ART UNIT

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1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/380,447	Applicant(s) SIDHU ET AL.	
	Examiner AMBER D. STEELE	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/15/07, 7/19/07, 4/7/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11,12,29-33,44-49,52-54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) 29,48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-9,11,12,30-33,44-47, 52-54, and 56-62 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

DETAILED ACTION

Status of the Claims

1. Claims 1-28 were originally filed on September 1, 1999.

The amendment to the claims received on February 26, 2004 amended claims 1 and 11-12; canceled claims 2, 5-6, 10, and 13-28; and added new claims 29-51.

The amendment to the claims received on June 14, 2004 amended claim 31; canceled claims 34-41, 43, and 50-51; and added new claims 52-54.

The amendment to the claims received on November 18, 2005 amended claims 1 and 31, canceled claim 42, and added new claims 55-58.

The amendment to the claims received on July 7, 2006 amended claims 3-4 and 44.

The amendment to the claims received on March 15, 2007 amended claims 1, 3-4, 7, 29-31, 44, and 56-58; canceled claim 55; and added new claims 59-62 (renumbered).

The amendment to the claims received on July 19, 2007 amended claims 4, 52-54, and 56-62.

Claims 1, 3-4, 7-9, 11-12, 29-33, 44-49, 52-54, and 56-62 are currently pending.

Claims 1, 3-4, 7-9, 11-12, 30-33, 44-47, 52-54, and 56-62 are currently under consideration.

Elections/Restrictions

2. Applicants elected, without traverse, gpVIII as the species of major coat protein (wild type SEQ ID NO: 2); position number/amino acid: 1/D, 2/K, 3/S, 4/E, 5/K, 6/F, 7/S, 8/R, 9/D,

Art Unit: 1639

11/Y, 12/E, 13/A, 14/L, 15/E, 16/D, 17/I, 18/I, 19/T, 20/N, 21/L, 22/F, 23/F, 24/L, 25/L, 26/G, 27/T, 28/V, 29/Y, 30/V for the variable residues; antibody as the species of heterologous protein, and SEQ ID NO: 110 as the species of linker in the reply filed on November 2, 2004. Claims 29 and 48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *non-elected species*, there being no allowable generic or linking claim. Please note: claims 52-54 have been rejoined upon further consideration.

Priority

3. The present application claims status as a National Stage application (i.e. 371) of PCT/US99/16596 filed July 22, 1999 which claims benefit of U.S. provisional applications 60/094,291 filed July 27, 1998; 60/103,514 filed October 8, 1998; 60/133,296 filed May 10, 1999; and 60/134,870 filed May 19, 1999.

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 60/133,296 and 60/094,291, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. U.S. provisional

Art Unit: 1639

applications 60/133,296 filed May 10, 1999 60/094,291 filed July 27, 1998 and fail to provide adequate support for a filamentous phage coat protein variant. Therefore, the present application has an effective filing date of October 8, 1998.

Sequence Compliance

5. The present application is still not fully compliant with the sequence rules. While SEQ ID NO: 2 has been inserted into the claims, a sequence with variable residues at positions 1-30 is not present. For example, a sequence with Xaa at position 1 wherein Xaa is E, L, V, Q, D, I, N, or A (i.e. wildtype) is not present in the sequence listing or claims.

Withdrawn Rejections

6. The written description rejection is withdrawn in view of the claim amendments.

7. The rejection of claims 1, 7-9, 11, 12, 30-32, 46, 47, 55, and 58 under 35 U.S.C. 103(a) as being unpatentable over Larocca et al. (US Patent 6,451,527 B1; *effective filing date of 08/29/1999*) in view of Li et al. (*J. Biol. Chem.*, **1993**, 268(7), pgs. 4584-4587) is withdrawn in view of the claim amendments.

New Objection

Claim Objections

8. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 52-54 and 56-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

Present claim 52 comprises subgenus/species that were not present in the originally filed specification. For example, residue number 1 variants of either D and I while being preferred substitutions (see page 41 of the present specification) does not encompass the preferred subgenus of D, I, or N. In addition, alanine at positions 7 and 9 is not listed in either the preferred substitutions or in the possible substitutions (see page 41).

Art Unit: 1639

Present claim 53, comprises subgenus/species that were not present in the originally filed specification. For example, residue number 11 variants of Y while being part of a preferred subgenus does not encompass the entire subgenus of Y, L, or F (see page 41). In addition, residue 14 being L was part of the sample substitution and not a preferred substitution. Furthermore, alanine at position 18 is not listed in either the preferred substitutions or in the possible substitutions (see pages 41-42).

Present claim 54, comprises subgenus/species that were not present in the originally filed specification. For example, isoleucine at residue 22 and methionine at residue 28 is not listed in either the preferred substitutions or in the possible substitutions (see page 42).

For present claims 56-62, the subgenus of variant residues found at pages 41-42 of the originally filed specification has been expanded by the claims (i.e. any amino acid substitution at the specified residues; see pages 41-42 of the present specification).

Furthermore, support for the open-ended ranges of at least 7, at least 8, and at least 10 or the range of 5-40 were not found.

See MPEP § 2163.05 regarding new matter and changes to the scope of the claims.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 4, 31, 45, 52-54, 56-59, and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, it is not clear if the claims

Art Unit: 1639

require the full-length sequence of the various SEQ ID NOs. If the claims were written as “the linking peptide comprising the amino acid sequence selected from the group consisting of...”, then the claim would require the full-length sequence of the SEQ ID NO: but still open to N-terminal or C-terminal additions (e.g. presently not clear if “is” is closed or open). Furthermore, it is not clear if the claims reciting SEQ ID NO: 2 require the other residues of sequence or only the residues which are varied (see the sequence compliance section above).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 3-4, 8-9, 11-12, 30-33, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deber et al., 1993, Val→Ala mutations selectively alter helix-helix packing in the transmembrane segment of phage M13 coat protein, PNAS, 90: 11648-11652 (provided by applicants in the IDS); Winter et al. U.S. Patent 5,858,657 (filed June 7, 1995); and Light et al. WO 94/05781 (published March 17, 1994).

For present claims 1, 3-4, and 30-31, Deber et al. teach M13 gVIII mutants with 3 variant residues including serine at position 27 (please refer to the entire reference particularly the abstract; Table 1; Figure 1).

However, Deber et al. does not teach fusion proteins.

For present claims 1, 3, 8-9, 11-12, 30-31, and 46-47, Winter et al. teach M13 gVIII fused to various scFvs comprising linkers for phage display wherein the phage can be propagated in host cells (please refer to the entire specification particularly the abstract; Figures 1-19; columns 11-13, 15, 18-19).

However, while Winter et al. teaches utilizing linkers between the two chains of the scFv, Winter et al. does not teach utilizing a linker between the coat protein and the other polypeptide of the fusion protein.

For present claims 44-45, Light et al. teach phage display utilizing linkers (please refer to the entire specification particularly pages 22-23, 28, 35, 40, 51).

Regarding claims 32-33, if the structure of the presently claimed invention and the invention as taught by Deber et al. and Winter et al. are the same, then the products are presumed to have the same inherent properties (e.g. hyperfunctional or hypofunctional; see MPEP § 2112).

The claims would have been obvious because a particular known technique (i.e. mutation of coat protein taught by Deber et al.; production of fusion proteins for phage display taught by Winter et al.; utilization of linkers in phage display taught by Light et al.) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

January 1, 2009